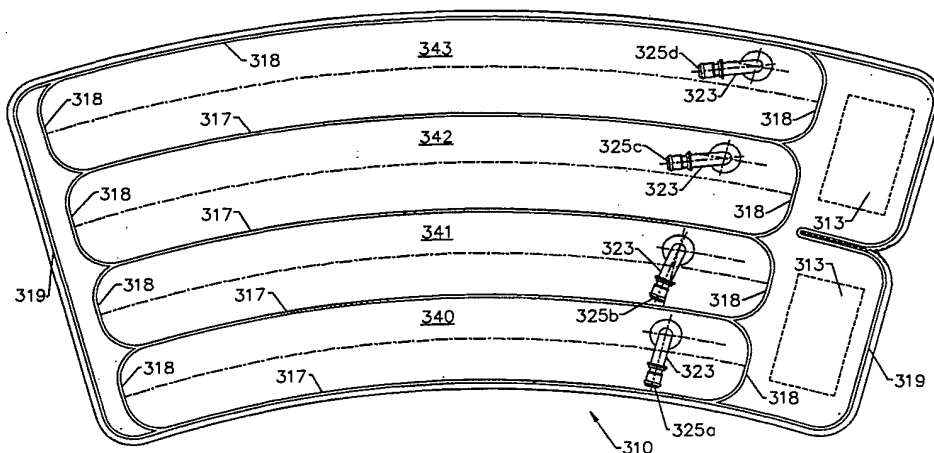




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/US95/03646 <b>(22) International Filing Date:</b> 29 March 1995 (29.03.95)  <b>(30) Priority Data:</b> 222,407                      5 April 1994 (05.04.94)                      US  <b>(71) Applicant:</b> JOBST INSTITUTE, INC. [US/US]; 5825 Carnegie Boulevard, P.O. Box 471048, Charlotte, NC 28247-1048 (US).  <b>(72) Inventors:</b> SANDMAN, Terry, L.; 5266 Nebraska Avenue, Toledo, OH 43615 (US). BOLAM, Kenneth, M.; 13001 Maple Springs Drive, Charlotte, NC 28278 (US). PEELER, Donald, H.; 6801 Linkside Court, Charlotte, NC 28277 (US).  <b>(74) Agents:</b> McCOY, Michael, D. et al.; Bell, Seltzer, Park & Gibson, P.O. Drawer 34009, Charlotte, NC 28234 (US).		<b>(81) Designated States:</b> European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

**(54) Title:** COMPRESSION SLEEVE FOR USE WITH A GRADIENT SEQUENTIAL COMPRESSION SYSTEM



**(57) Abstract**

A compression system for applying gradient sequential compression of a patient's limb and accelerating deep venous blood flow in the limb from a source of pressurized fluid is provided. The system includes a means for supplying a source of pressurized fluid, said source having a connector interface comprising at least one outlet port, a connector for providing a continuous fluid passageway between the source of pressurized fluid and a compression sleeve. The compression sleeve (310) includes a pair of dimensionally stable, flexible sheets of fluid impervious material, said sheets comprising a thermoplastic film and a fabric applied together into a unitary sheet and means for securing the thermoplastic films of said sheets together along lines (317, 318) defining at least one inflatable chamber (340, 341, 342, 343), disposed longitudinally along the sleeve. A fitting (323) is secured to one of the thermoplastic films of each chamber and in fluid communication with a source of pressurized fluid for inflating the chamber. There is also provided a means (313) for releasably securing the sleeve around the limb of a patient with the chamber encircling the limb.

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## COMPRESSION SLEEVE FOR USE WITH A GRADIENT SEQUENTIAL COMPRESSION SYSTEM

### BACKGROUND OF THE INVENTION

#### Field Of The Invention

The present invention relates to a compression sleeve for use with a system for  
5 intermittently squeezing a patient's limb to accelerate the flow of blood therein. More particularly, the present invention relates to a compression system having a means for providing a pressurized fluid, a compression sleeve for applying gradient sequential  
10 compression to a patient's limb, and a connector for providing fluid flow between the pressurized source and the sleeve.

#### Description Of The Prior Art

External pneumatic leg compression reduces  
15 venous stasis by intermittently squeezing the leg and accelerating deep venous blood flow. It also enhances blood fibrinolytic activity. Intermittent compression of the leg is effective against venous thrombosis in patients undergoing many types of surgery. The usual  
20 treatment is to wrap compressive sleeves having a plurality of pressure compartments around the limb of a patient and then intermittently pressurize the sleeve to successively apply pressure compression to different parts of the limb.

25 The prior art devices include a variety of compression devices which provide pressure against a

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patient's limb through a pressure sleeve which encircles the patient's limb. One of the shortcomings of the compression devices of the prior art is that the chambers of each sleeve are not capable of independent  
5 inflation. In some devices pressurized fluid is fed to a first chamber and after a partial inflation air flows to an adjacent chamber through a foam-filled conduit. Another disadvantage of some of the compression sleeves of the prior art is that the devices use air vent  
10 openings on the inner side of the sleeve next to the patient's limb to ventilate the limb so that the sleeve will be comfortable. The construction of sleeves of the prior art has been to place an outer sheet over an inner thermoplastic sheet secured only at limited  
15 areas. Such sleeve construction does not have good dimensional stability and thus does not retain the best shape during use. In addition, another disadvantage of many of the prior sleeves is that they are not sealed at their outer edges. Yet another disadvantage of the  
20 prior art compression sleeves is that some of them do not fit snugly around the patient's limb because the side edges of the sleeve or chamber form a straight line.

#### SUMMARY OF THE INVENTION

25 With the foregoing in mind it is therefore a general object of the present invention to provide a compression sleeve for use in a system for preventing the occurrence of deep vein thrombosis and pulmonary embolism in recumbent patients.

30 Another object of the present invention is to provide a compression system for gradient sequential compression of a patient's limb and accelerating deep venous blood flow therein.

Yet another object of this invention is to  
35 provide a compression sleeve made from dimensionally

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stable flexible sheets of fluid impervious layers laminated together into a unitary sheet.

It is yet another object of the present invention to provide a compression sleeve having an inflatable chamber shaped in an arcuate manner to more comfortably fit the patient's limb during use.

It is a further object of the present invention to provide a compression sleeve for use in a system and method of regulating compressive forces applied to a limb of a user.

These objects are accomplished by the present invention in which a system for gradient sequential compression of a patient's limb and accelerating deep venous blood flow therein is set forth which provides cyclical squeezing and relaxing action to one or more limbs of a patient. This occurs by sequentially establishing a decreasing gradient of compressive forces along the limbs in a proximal direction. Broadly, the device includes a controller system having a pneumatic compressor, a multi-tube connector and at least one compression sleeve having inflatable chambers encircling (or substantially encircling) a patient's limb.

In particular, the compression system includes one or more sleeves (e.g., calf, thigh, calf and thigh, etc.) which can be wrapped around and releasably secured to a limb of a patient. The sleeves have one or more inflatable chambers therein for retaining pressurized fluid upon inflation and for applying a compressive force to a limb. The compression system also includes a system controller for controlling transfers of pressurized fluid to the inflatable chambers of the compression sleeves during respective inflation cycles, and for venting the pressurized air during respective deflation cycles. Transfers of fluid from the system controller to the

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sleeves is preferably provided by a connector having one or more tubes or conduits.

The compression sleeve for applying compressive pressures against a patient's limb includes  
5 a pair of dimensionally stable, flexible sheets of fluid impervious material, said sheets comprising a thermoplastic film and a fabric applied together into a unitary sheet such as by laminating. The thermoplastic films are sealed together, such as by conventional heat  
10 sealing or other well known means, along lines defining at least one elongated inflatable chamber disposed longitudinally along the sleeve. A fitting is secured to one of the thermoplastic films of each chamber and in fluid communication with a source of pressurized  
15 fluid for inflating the chamber. The sleeve has a fastener for releasably securing it around the limb of a patient with the chamber encircling the limb.

According to another aspect of the invention, compressive forces are applied to a limb of a patient  
20 by sequentially compressing a distal portion and relatively proximal portion of the limb to provide respective first and second radially inwardly directed compressive forces thereto. The first compressive force is maintained above the second compressive force  
25 so that a decreasing pressure gradient is established in a proximal direction along the limb for a preselected time interval. The force is preferably maintained by measuring the compressive forces and adjusting (i.e., increasing or decreasing) the  
30 compressive forces to maintain predetermined forces in each sleeve chamber.

In operation, compressive forces are applied to a limb of a patient using a multi-chambered inflatable limb sleeve surrounding the limb. The  
35 method includes the steps of pressurizing a first chamber of the limb sleeve to a first predetermined chamber pressure and then pressurizing a second

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chamber, disposed proximally relative to the first chamber, to a second preselected chamber pressure, after the first chamber reaches a first threshold pressure. The second threshold pressure may be less  
5 than or equal the first predetermined pressure.

Preferably, the second chamber pressurizing step occurs after a pressure in the first chamber has been established at the first predetermined pressure for at least a first time interval. A step is also  
10 performed to regulate the pressure in the first and second chambers at their respective predetermined pressures, so that a pressure gradient is established therebetween. The regulating step may also include the steps of measuring a pressure in the first chamber  
15 while preventing depressurization of the second chamber and vice versa. Additionally, the regulating step may include the steps of measuring a pressure in the first chamber after it has been inflated to the first threshold pressure and then remeasuring a pressure in  
20 the first chamber, after the second chamber has been inflated to the second threshold pressure.

The pressures in the chambers may also be adjusted by performing periodic reinflating steps. Similar steps may also be performed to inflate third  
25 and fourth, etc. chambers of the limb sleeve, in sequence, so that a monotonically decreasing pressure gradient is established between the chambers of a sleeve.

#### BRIEF DESCRIPTION OF THE DRAWINGS

30 Other objects, features and advantages of the present invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings in which:

FIG. 1 is a fragmentary perspective view of  
35 the compression system of the present invention;

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FIG. 2 is a perspective view illustrating the system controller of the present invention with the housing cover removed;

FIG. 3 is an exploded perspective partial  
5 view of the multi-tube connector of the present invention;

FIG. 4 is a front plan view of a compression sleeve for use with the compression system of the present invention;

10 FIG. 5 is a back plan view of a compression sleeve for use with the compression system of the present invention;

FIG. 6 is a fragmentary section view of a compression sleeve of the present invention taken along  
15 line 6-6 of FIG. 4; and

FIG. 7 is a front plan view of an alternative embodiment of a compression sleeve for use with the compression system of the present invention.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

20 The compression system includes a controller for performing, among other things, real time inflation, monitoring, adjusting and deflation of pneumatic sleeves for gradient sequential compression of a patient's limb and accelerating deep venous blood  
25 flow therein. Referring now to FIG. 1, the gradient sequential compression system of the present invention comprises broadly, a controller 10, a pair of multi-tube conduit connectors 100 coupled to a pair of inflatable four chamber compression sleeves 210 which  
30 apply gradient sequential compression against a patient's limb.

Referring now more specifically to FIG. 2 there is shown a perspective view of a preferred embodiment of the system controller of the present  
35 invention generally indicated at 10. As shown in FIG. 2 the system controller 10 includes a housing forming a



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base 11 and a cover 13. The housing includes a control display panel 15, tube connector outlet ports 17, and a mounting means 19. The control display panel 15 is used to visually communicate chamber inflation information (e.g., pressure levels, chamber status), the mode of operation (e.g., one- or two-limb mode) and alarm, alert and fault conditions. The display may also provide means, responsive to actuation by a user or health care professional, for preselecting the desired pressure levels to be achieved during a sleeve inflation cycle. The system controller 10 includes a pneumatic compressor 20 for supplying compressed fluid through valve manifold 30 having a plurality of valves which connect through outlet ports 17.

As shown in FIG. 3, a conduit connector 100 is provided for rapidly connecting and disconnecting to the controller 10 at outlet ports 17 and to one or more inflatable compression sleeves 210 of the present invention for applying gradient sequential compressive pressures against a patient's limb. The conduit connector 100 includes flexible conduits 110, connector inserts 120, couplers 130 and gripping member 140. In a preferred embodiment, the connector 100 interacts with the outlet ports 17 of controller 10 for interconnecting with each of the sleeves 210, one for each leg of the patient.

Flexible conduit 110 comprises a plurality of integrally formed tubes 111 in spaced-apart relation. The flexibility of the conduit 110 allows a user to select a position for the controller 10 which is comfortable for the patient and accessible to the operator while conforming to the space available for operating the compression system of the present invention.

In a preferred embodiment, the conduit 110 is made of soft plastic, such as polyvinyl chloride, and comprises four thin-walled tubes 111 of generally

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circular cross-section having a first end 115a and a second end 115b. Tubes 111 define pneumatic passageways for interconnecting each outlet port 17 of the controller 10 to a respective inlet port 223 for each chamber 240, 241 of sleeve 210 (FIG. 4).

At a first end 115a, connector 100 includes a plurality of hollow generally cylindrical connector inserts 120. The number of connector inserts 120 corresponds to the number of tubes 111 in conduit 110. Connector inserts 120 may be secured to the ends 115a of tubes 111 by any suitable means, but are preferably press fit. O-rings 129 form a tight seal with the receiving holes in outlet ports 17 to prevent the pressurized air from escaping at the connections between connector inserts 120 and outlet ports 17.

At a second end 115b, connector 100 includes a plurality of longitudinally-spaced sequential quick release couplers 130. Couplers 130 may be of the type described in United States Patent No. 5,052,725 and do not form a part of the present invention. The number of couplers 130, however, corresponds to the number of tubes 111 in conduit ribbon 110. Couplers 130 are secured to tubes 111 at second end 115b by any suitable means such that couplers 130 are not easily removed from tubes 111.

Each of tubes 111 has a predetermined length such that couplers 130 are spaced-apart at longitudinal positions which accommodate the locations of the chambers 240, 241 in sleeve 210 (FIG. 4). In a preferred embodiment, conduit 110 is divided at second end 115b into four separate longitudinally-spaced ends which are secured to couplers 130 corresponding to each of four tubes 111. In operation, couplers 130 are releasably attached to corresponding fittings 223 in chambers 240, 241 to define pneumatic passageways for interconnecting controller 10 and compression sleeve 210 (FIG. 4). Each coupler 130 includes printed

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indicia 133 on the body 135 of the coupler which corresponds to like printed indicia 226 on fittings 223 in chambers 240, 241. Thus, when couplers 130 are properly connected to the corresponding fittings in sleeve 210, a continuous pneumatic passageway is formed for interconnecting controller 10 and sleeve 210 to accomplish the objectives of the invention in accordance with the aforementioned sequence. In a preferred embodiment, printed indicia 133 and printed indicia 226 are predetermined colors such that couplers 130 and inlet ports 223 in chambers 240, 241 are color-coded.

A gripping member 140 is positioned adjacent first end 115a of connector 100 for aligning conduit inserts 120 with outlet ports 17 of controller 10. Gripping member 140 includes a housing formed by top portion 143a and bottom portion 143b. Portions 143a and 143b are preferably molded of a suitable plastic, but may be formed by any means which accomplish the objectives of the invention described hereafter. Top portion 143a and bottom portion 143b are joined together to form the housing. The pneumatic passageways formed thereby provide a continuous passageway for permitting the compressed air from the controller 10 to flow into the chambers 240, 241 in sleeve 210 to inflate the chambers in the aforementioned sequence without directly contacting the grip.

Portions 143a and 143b include latching members 180 having inclined gripping surfaces on exterior surfaces. Latching members 180 are formed integrally, for example by molding, with portions 143a and 143b such that the latching members pivot about a resilient joint formed along an axis perpendicular to the direction in which conduit 110 passes through gripping member 140. Latching members 180 are thereby inwardly and outwardly movable in relation to portions

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143a and 143b. Latching members 180 include latching lips 185 which interact with slots 18 (FIG. 2) in connector outlet ports 17 for securing gripping member 140, and thus conduit 110, to controller 10. The  
5 interaction between latching lips 185 and slots 18 thereby formed provides further transfer of the tensile stresses induced in conduit 110 through gripping member 140 to controller 10.

A user secures connector 100 to controller 10  
10 at first end 115a by first squeezing latching members 180, then inserting gripping member 140 into controller outlet port 17 until latching lips 185 interact with slots 18, and then releasing the latching members so that the latching lips engage slots 18 in controller  
15 outlet port 17.

Referring now to FIG. 4, the compression sleeve 210 includes a pair of inflatable chambers 240, 241 suitable to encircle a patient's limb and adapted to render compressive pressures thereto. As shown more  
20 clearly shown in FIG 6., the sleeves are formed from a pair of dimensionally stable, flexible sheets 220, 221. Each sheet is made of a soft fabric having a thermoplastic film 211 laminated or applied across its entire surface to form a dimensionally stable and  
25 unitary sheet. Alternatively, the sleeve can be a dimensionally stable film having a surface treatment. The thermoplastic film 211 may be formed from a suitable fluid impervious flexible thermoplastic material, such as polyvinylchloride or other suitable  
30 thermoplastic. The fabric 212 may be a relatively inelastic fabric of nylon or polyester. It is desirable to use a fabric of a suitable color and preferably a fabric with a brushed matte or napped finish. While nonwoven fabrics may be used, it is  
35 preferable to use a knitted fabric. As will be discussed in greater detail hereinafter, a portion of the fabric may serve as one part of the fastener. It

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is sometimes desirable that the fabric 212 covers less than the entire surface of the thermoplastic film 211. In such cases, a non-napped fabric may be laminated to the thermoplastic film and still provide an attractive and comfortable fabric surface for the sleeve.

The sleeve 210 has a pair of side edges 214a and 214b, and a pair of end edges 216a and 216b connecting the side edges 214a and 214b. The sheets 220, 221 are juxtaposed one on the other at their respective edges and ends with the thermoplastic film 211 facing each other. The sheets 220 and 221 are then sealed together along longitudinal lines 217 and lateral lines 218 to form a plurality of longitudinally disposed elongated inflatable airtight chambers 240, 241 adjacent each other. The chambers 240, 241 extend laterally in the sheets 220 and 221, and are disposed in the longitudinal arrangement between end edges 216a and 216b. In addition, the compression sleeve 210 is sealed at seam 219 around the outer periphery of juxtaposed sheets 220 and 221. When the compression sleeve is sealed at its outer edges by seam 219 the areas of the sleeve outside of the chambers are protected from intrusion of foreign material between the sheets, the area of the fastener is stabilized. When the sleeve 210 is placed on a patient's calf, the lowermost chamber 240 is located on a lower part of the leg near the patient's ankle, while the uppermost chamber 241 is located on an upper part of the leg nearer the knee.

The construction of the sleeve 210 is accomplished by any one or the combination of heat sealing, ultrasonic sealing, sewing, adhesives and the like. There is thus formed a compression sleeve, formed from unitary sheets, having a plurality of chambers 240, 241 which, as shown in FIG. 4 are adjacent each other. As shown in FIGS. 4-6, there may be some space between the adjacent chambers or the

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chambers may share a common seam. The distance between the chambers is a matter of choice depending upon the size of the sleeve and the location on the patient's limb. In an alternative embodiment of the compression sleeve of this invention, each chamber of the sleeve may, if desired, have a different volume which can be adapted to conform to the chamber location on the patient's limb. The pressure in each chamber of differing volumes remains the same because the pressure exerted by each chamber is individually controlled. As shown in FIGS. 4 and 5, in a preferred embodiment, the sleeve 210 and the chambers 240, 241 may be arcuately shaped to better fit the patient's limb. In addition, it is not necessary that the inflatable chambers occupy the entire longitudinal portion of the sleeve from end edge to end edge. For example, as shown in FIG. 4, the chambers only occupy a majority portion of the sleeve leaving the remainder to be used for other purposes, such as providing a place for positioning a first portion of the fastening means.

Each sleeve 210 has a fastening means for securing the sleeve around the patient's limb. In a preferred embodiment, the fastening means comprises a fastener strip 213 of connecting tabs extending along side edge 216a of a surface of the sleeve and being releasably engagable to the fabric 212 (depending upon which side of the sleeve the fastener strip 213 is located). The elongated fastener strip 213 may be a hook and loop-type fastening material, such as Velcro®. The fastener strips 213 are preferably affixed to the tabs located on the center line of each chamber 240, 241 to provide more stability of the chamber when the sleeve is secured around the patient's limb. The fastener strip 213 occupies substantially the entire length of an end edge of a sleeve. In one embodiment of this invention, the fastener strip 213 is connected to the tab portion in an area outside of the chamber.

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The dimensional stability provided by the laminated sheets enables the fastener strip, when placed outside the chambers to function without having the ends of the chambers overlaying each other.

5           Each chamber 240, 241 has a conventional quick release polycarbonate fitting 223 for rapid connection of couplings 130 to its respective conduit tube 111. Each fitting 223 has attached to it printed indicia 226 to match the indicia 133 on the conduit  
10 coupling 130. The fitting 223 is preferably secured in place to thermoplastic film 211 by well known means, such as heat sealing. The fluid inlets to chamber fittings 223 may be disposed in line with each other but the fluid inlets 225a and 225b are preferably  
15 disposed at angles for most conveniently accommodating each coupler 130 of conduit 110. A separation or slit 225 is provided at end edge 216a substantially coinciding with the region between adjacent chambers to promote a better fit on the patient's limb.

20           In another embodiment, the compression sleeve 310 shown in Figure 7 has four chambers 340, 341, 342, 343 suitable to encircle a patient's limb and adapted to render compressive pressure thereto. The compression sleeve 310 has the four chambers, but is  
25 otherwise made like and operates like the two chambered sleeve 210 described in FIGS. 4-6. For example, a compression sleeve 310 is formed from a pair of dimensionally stable, flexible sheets with the thermoplastic films facing each other and sealed  
30 together along longitudinal lines 317 and lateral lines 318 to form four longitudinally disposed inflatable airtight chambers adjacent each other. The compression sleeve may also be sealed at its outer edges at seam 319. The compression sleeve 310 may be secured around  
35 the patient's limb in a manner similar to compression sleeve 210 using fastening strips 313 located on tabs at one end edge of the sleeve. Each chamber has a

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conventional quick release fitting 323 for rapid connection to couplings 130. The fluid inlet 325a, 325b, 325c and 325d to each respective fitting may be disposed at a different angle to each other to better  
5 accommodate the multi-tube connector.

In operation, the sleeve 210 is wrapped around the calf or thigh and releasably secured. In use, the sleeve 210 may be placed below the patient's leg preparatory for securing the limb. Next, the first  
10 fastener means and the second fastener means are passed around the patient's leg. After both the thigh and calf sleeve have been suitably wrapped around the patient's limb, the remaining part of the sleeve adjacent the side edge may be wrapped over the fabric  
15 and the fastener strip 213 may be pressed against the fabric 212. Thus, the fastener strip 213 engages with the brushed fiber of the fabric 212 such that the strips and the sheet engage and retain the sleeve in wrapped configuration. Since the fabric 212 extends  
20 entirely across the outer surface of the sleeve 210, the sleeve may be readily adjustable, as necessary, for the desired fit according to the size of the patient's limb.

After placement of the sleeve on the  
25 patient's limb and attached via connector 100 to the controller 10, the controller may be initiated in order to sequentially supply fluid to the chambers of compression sleeve 210 or compression sleeve 310. Of course, it is understood that there may be sleeves on  
30 each of the patient's legs. The controller 10 intermittently inflates the chambers during periodic compression cycles, and intermittently deflates the chambers through the connector tubes during intermediate decompression cycles as described above.

35 While the preferred embodiments of this invention have been illustrated in detail, it should be readily apparent to those skilled in the art that other



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embodiments may be conceived and fabricated without departing from the spirit and scope of this invention.

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## THAT WHICH IS CLAIMED:

1. A compression system for applying gradient sequential compression of a patient's limb and accelerating deep venous blood flow in the limb from a source of pressurized fluid, comprising:
  - 5 a means for supplying a source of pressurized fluid, said source having a connector interface comprising at least one outlet port;
  - a connector for providing a continuous fluid passageway between said connector interface and a
  - 10 compression sleeve for providing a source of pressurized fluid, said compression sleeve comprising;
    - an elongated pressure sleeve comprising a pair of dimensionally stable, flexible sheets of fluid impervious material, said sheets comprising a
    - 15 thermoplastic film and a fabric applied together into a unitary sheet, said thermoplastic films of said pair of sheets being secured together along lines defining at least one inflatable chamber disposed longitudinally along the sleeve;
    - 20 a fitting secured to one of the thermoplastic films of each chamber and in fluid communication with a source of pressurized fluid for inflating the chamber; and
    - means for releasably securing said sleeve
    - 25 around the limb of a patient with the chamber encircling the limb.
2. The compression system for applying gradient sequential compression of a patient's limb and accelerating deep venous blood flow in the limb from a
- 30 source of pressurized fluid according to Claim 1 wherein said means releasably securing said sleeve comprises fastening means placed on the outside of and proximate one edge of the sleeve for attachment to said fabric of the sleeve after it is wrapped around the
- 35 limb of a patient.

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3. The compression system for applying gradient sequential compression of a patient's limb and accelerating deep venous blood flow in the limb from a source of pressurized fluid according to Claim 1  
5 wherein said at least one inflatable chamber is a plurality of chambers and said fitting secured to a chamber is a fitting for each chamber for connection to the multi-tube conduit couplers.

4. The compression system for applying  
10 gradient sequential compression of a patient's limb and accelerating deep venous blood flow in the limb from a source of pressurized fluid according to Claim 1 wherein said fastening means is formed of a fastening strip of connecting tabs formed at one side edge of  
15 said sleeve and said tabs are located at the center line of a pair of adjacent chambers.

5. The compression system for applying gradient sequential compression of a patient's limb and accelerating deep venous blood flow in the limb from a  
20 source of pressurized fluid according to Claim 1 wherein said chamber defined by the sheets occupies a majority of the sleeve but leaves a sufficient portion to support a fastening area outside the area defining the chamber.

25 6. The compression system for applying gradient sequential compression of a patient's limb and accelerating deep venous blood flow in the limb from a source of pressurized fluid according to Claim 1 wherein one portion of the securing means is connected  
30 to a sleeve portion outside of the area defined by the chamber.

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7. The compression system for applying gradient sequential compression of a patient's limb and accelerating deep venous blood flow in the limb from a source of pressurized fluid according to Claim 1  
5 further comprising said sleeve having at one end edge a separation between the tabs substantially coinciding with the region between adjacent chambers.

8. The compression system for applying gradient sequential compression of a patient's limb and  
10 accelerating deep venous blood flow in the limb from a source of pressurized fluid according to Claim 1 wherein said fastener means is a hook and loop-type fastener.

9. The compression system for applying  
15 gradient sequential compression of a patient's limb and accelerating deep venous blood flow in the limb from a source of pressurized fluid according to Claim 1 wherein the chambers are immediately adjacent each other, separated only by means for connecting  
20 thermoplastic films.

10. A sleeve for applying compressive pressures against a patient's limb and accelerating deep venous blood flow therein from a source of pressurized fluid, comprising:  
25 a pair of dimensionally stable, flexible sheets of fluid impervious material, said sheets comprising a thermoplastic film and a fabric applied together into a unitary sheet, said thermoplastic films of said pair of sheets being secured together along  
30 lines defining at least one inflatable chamber disposed longitudinally along the sleeve;  
a fitting secured to one of the thermoplastic films of each chamber and in fluid communication with a

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source of pressurized fluid for inflating the chamber through a connector; and

means for releasably securing said sleeve around the limb of a patient with the chamber  
5 encircling the limb.

11. The sleeve for applying compressive pressures against a patient's limb according to Claim 10 wherein said securing means comprises fastening strip placed on the outside of and proximate one edge  
10 of said sleeve for attachment to said fabric of said sleeve after said sleeve is wrapped around the limb of a patient.

12. The sleeve for applying compressive pressures against a patient's limb according to Claim  
15 10 wherein said fastening means is formed of a fastening means located on the center line of a chamber.

13. The sleeve for applying compressive pressures against a patient's limb according to Claim  
20 10 wherein said at least one inflatable chamber is a plurality of chambers and said fitting secured to a chamber is a fitting for each chamber.

14. The sleeve for applying compressive pressures against a patient's limb according to Claim  
25 13 wherein said fittings are oriented at angles with respect to one another to more easily accommodate said connector.

15. The sleeve for applying compressive pressures against a patient's limb according to Claim  
30 13 wherein said fittings are oriented at different angles with respect to one another to more easily accommodate said connector.

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16. The sleeve for applying compressive pressures against a patient's limb according to Claim 10 wherein said fastening means is formed of a fastening strip of connecting tabs formed at one side edge of said sleeve and said tabs located at the center lines of a pair of adjacent chambers.

17. The sleeve for applying compressive pressures against a patient's limb according to Claim 10 wherein each chamber of the sleeve has a different internal volume.

18. The sleeve for applying compressive pressures against a patient's limb according to Claim 10 wherein the sleeve has a pair of opposed edges having an arcuate shape.

19. The sleeve for applying compressive pressures against a patient's limb according to Claim 10 wherein the chamber is arcuate shaped.

20. The sleeve for applying compressive pressures against a patient's limb according to Claim 10 wherein the chamber defined by the sheets occupies a majority of the sleeve but leaves a sufficient portion to support a fastening area outside the area defining the chamber.

21. The sleeve for applying compressive pressures against a patient's limb according to Claim 10 wherein the chambers are immediately adjacent each other, separated only by means for connecting thermoplastic films.

22. The sleeve for applying compressive pressures against a patient's limb according to Claim 10 wherein said chambers are of different lengths.

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23. The sleeve for applying compressive pressures against a patient's limb according to Claim 10 wherein one portion of the securing means is connected to a sleeve portion outside of the area  
5 defined by the chamber.

24. The sleeve for applying compressive pressures against a patient's limb according to Claim 10 wherein said sleeve has two chambers.

25. The sleeve for applying compressive  
10 pressures against a patient's limb according to Claim 24 further comprising said sleeve having at one end edge a separation between the tabs substantially coinciding with the region between adjacent chambers.

26. The sleeve for applying compressive  
15 pressures against a patient's limb according to Claim 10 wherein said sleeve has four chambers.

27. The sleeve for applying compressive pressures against a patient's limb according to Claim 10 wherein said fastener means is a hook and loop-type  
20 fastener.

28. The sleeve for applying compressive pressures against a patient's limb according to Claim 10 wherein said pairs of dimensionally stable sleeves are connected together at their side edges and end  
25 edges.

29. A sleeve for applying compressive pressures against a patient's limb and accelerating deep vein blood flow therein from a source of pressurized fluid, comprising:  
30 a pair of dimensionally stable, flexible sheets of fluid impervious material having a pair of

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side edges, and a pair of end edges connecting said side edges, said sheets comprising a thermoplastic film and a fabric applied together into a unitary sheet, said thermoplastic films of said pair of sheets being  
5 secured together along lines defining a plurality of inflatable chambers disposed longitudinally along the sleeve;

a plurality of fittings one each secured to one of the thermoplastic films of each chamber and in  
10 fluid communication with a plurality of conduits for receiving a source of pressurized fluid for inflating each chamber through a connector; and

means for releasably securing said sleeve around the limb of a patient with the chambers  
15 encircling the limb, said means comprising fastening strips placed on the outside of and proximate one edge of the sleeve for attachment to said fabric of said sleeve after said sleeve is wrapped around the limb of a patient.



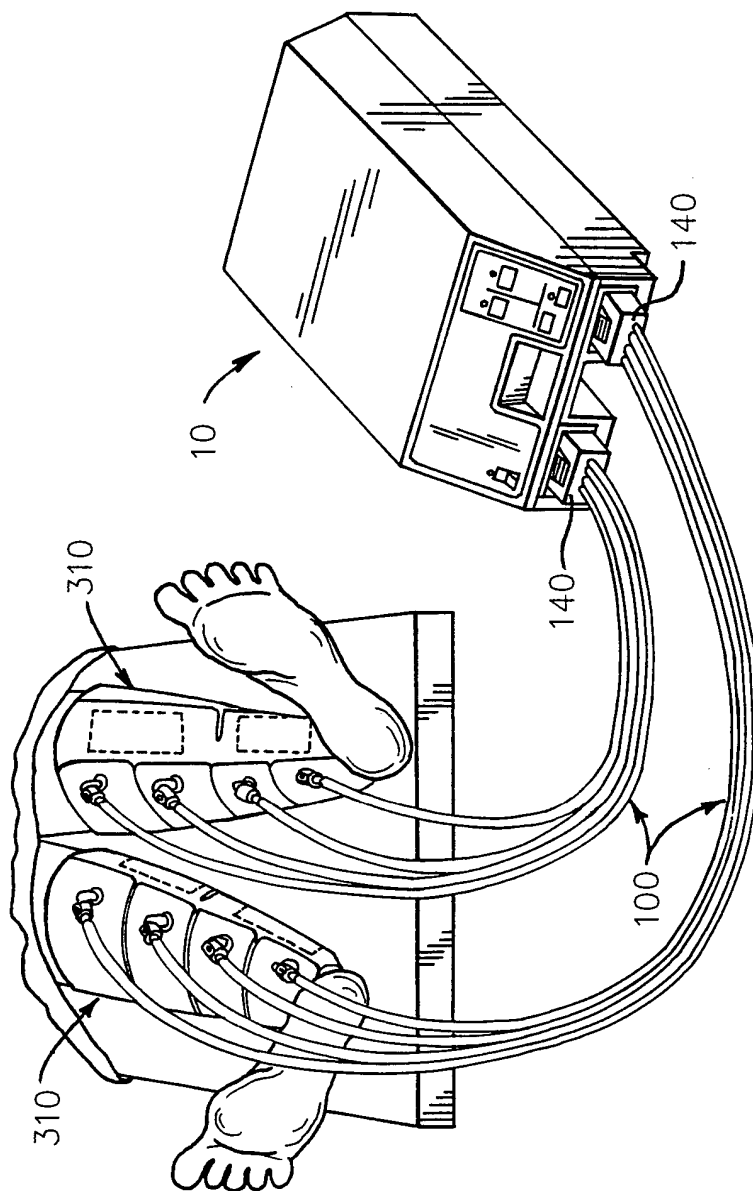
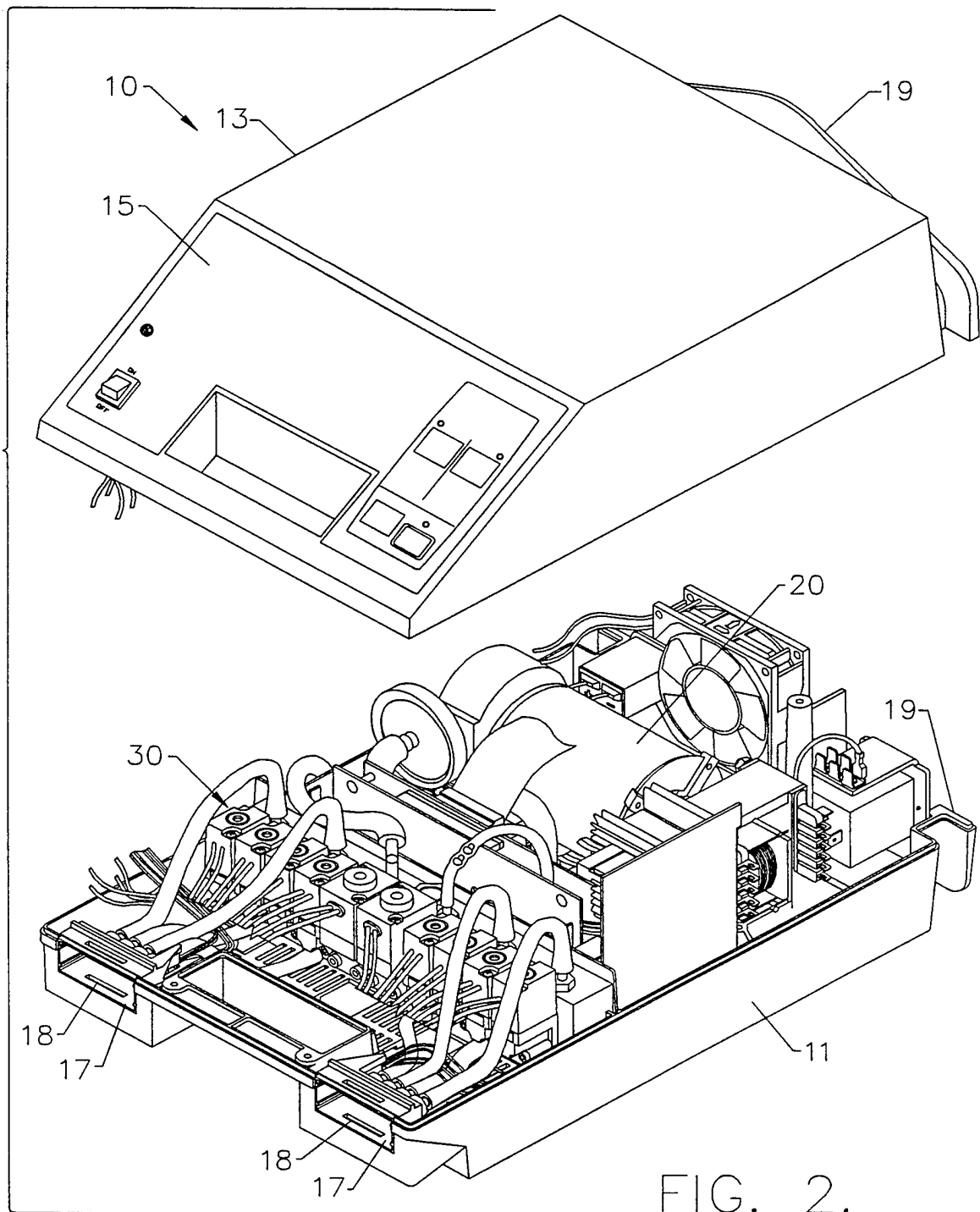
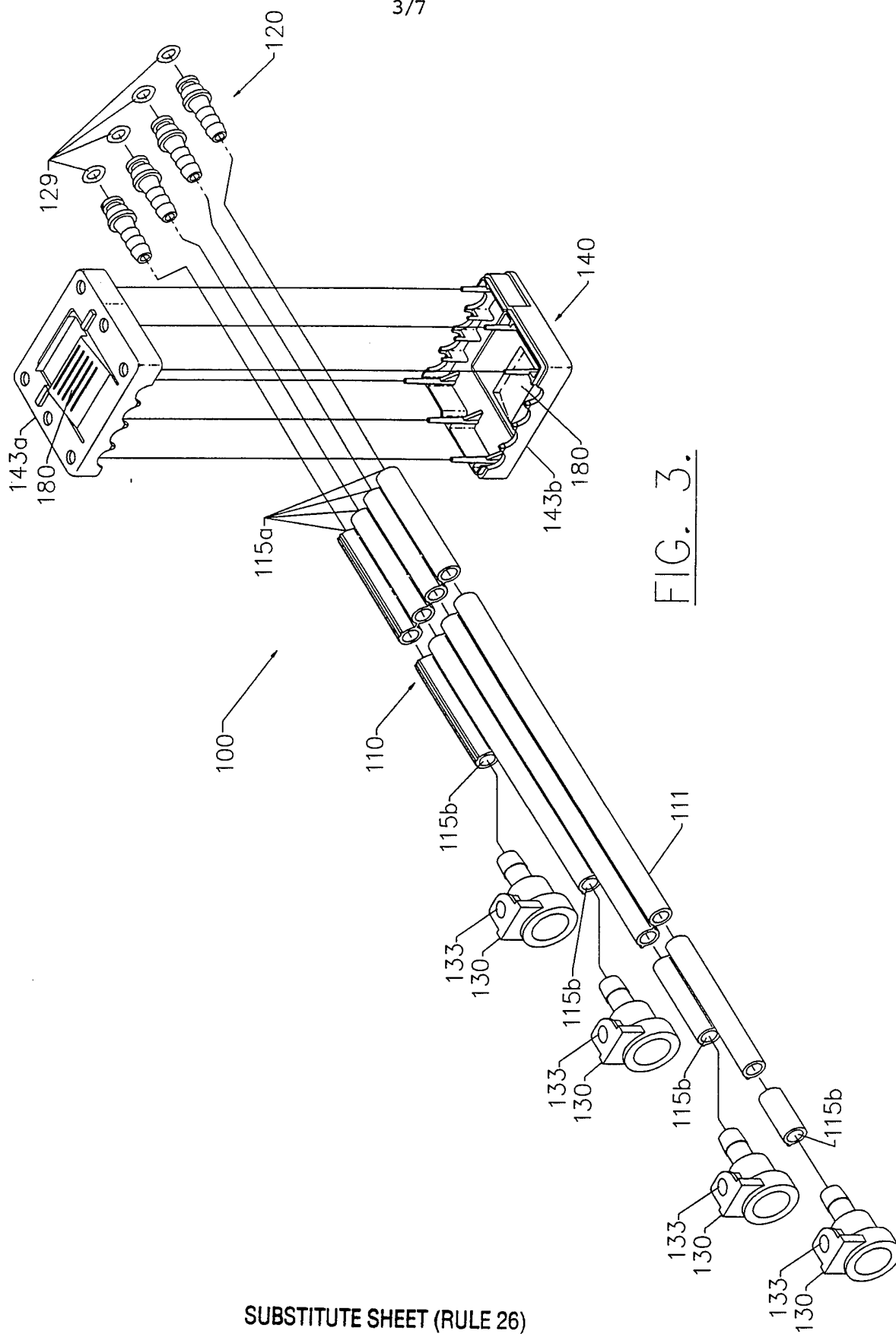


FIG. 1.



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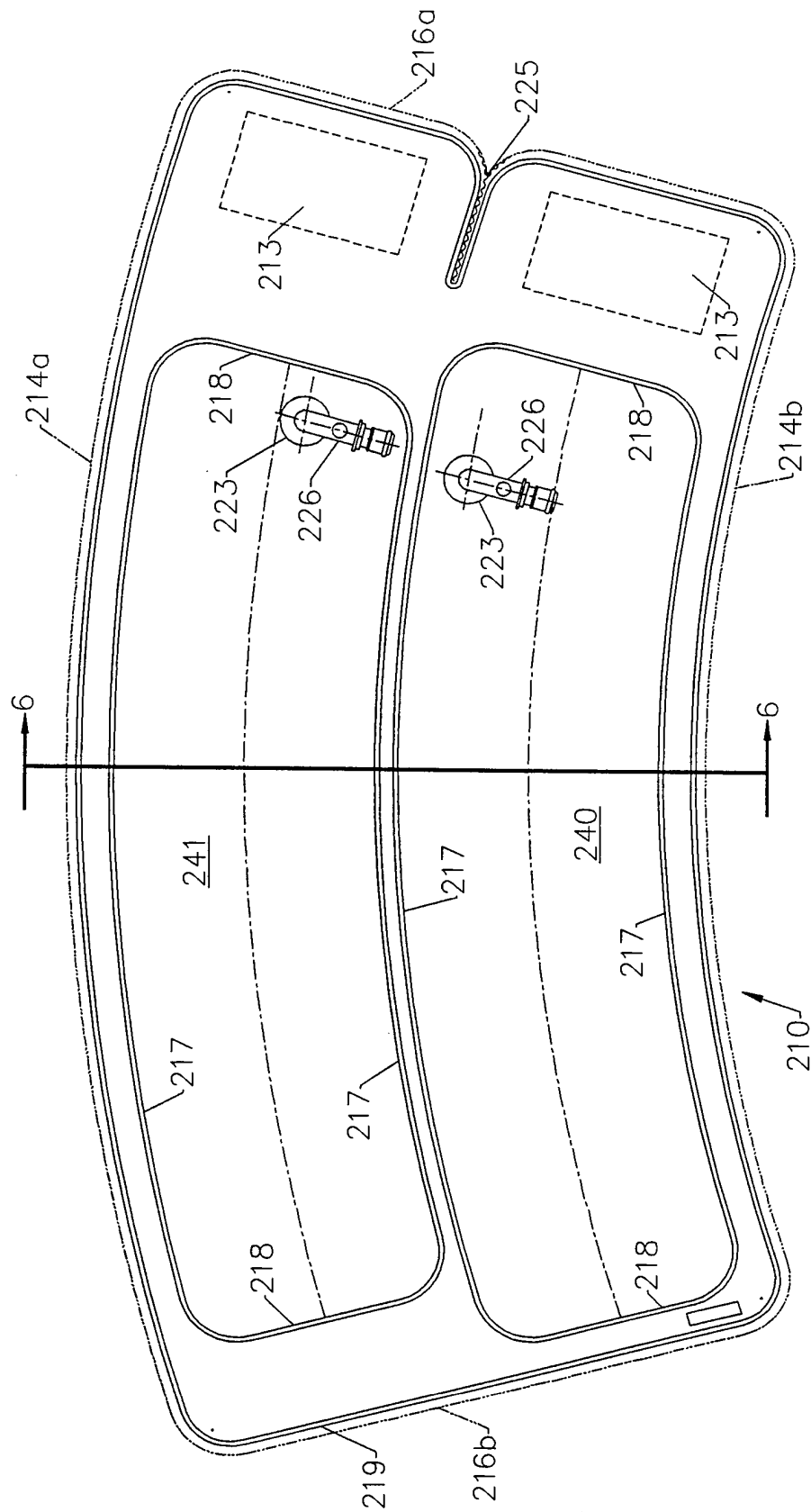


FIG. 4.

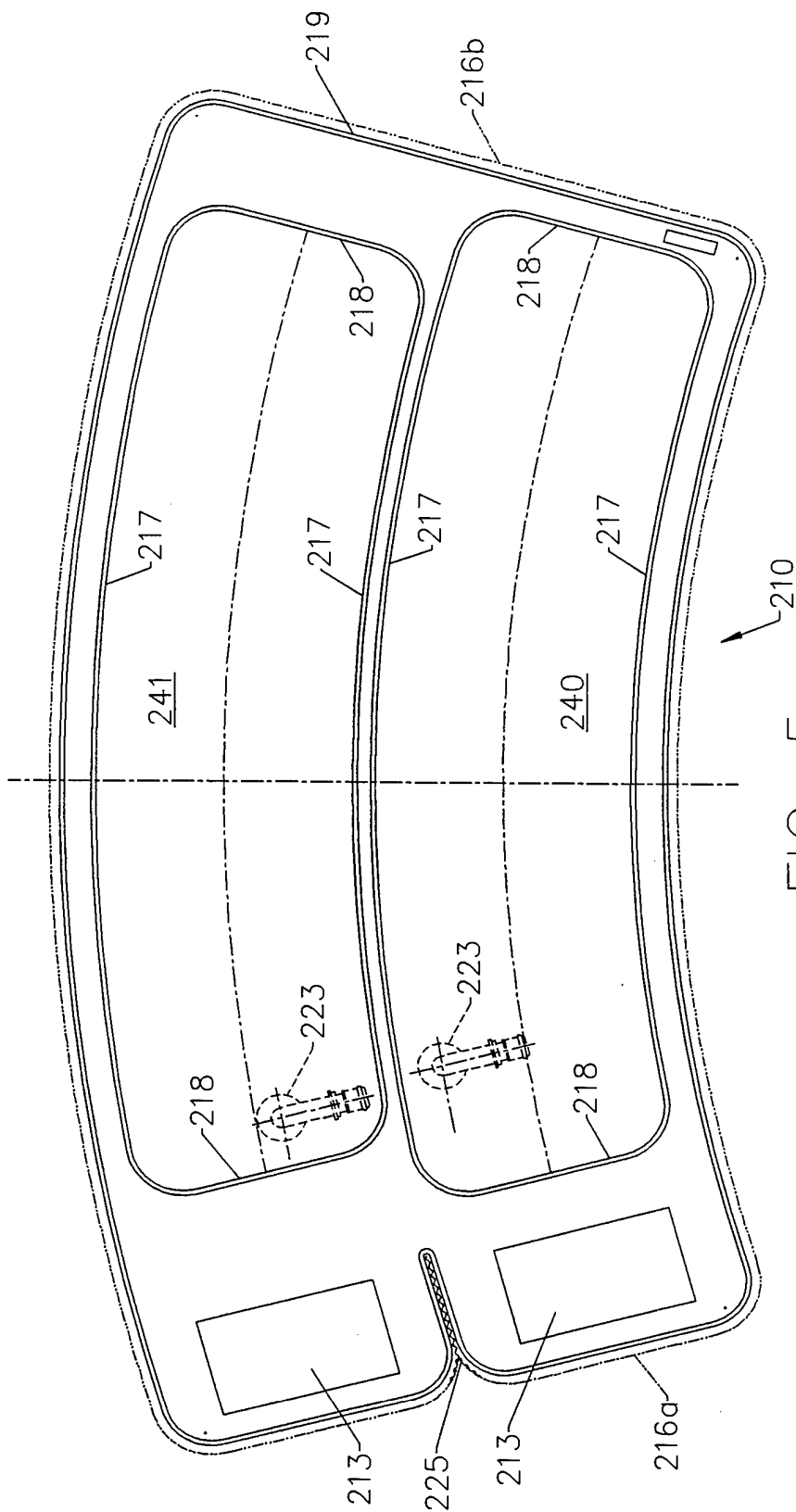


FIG. 5.

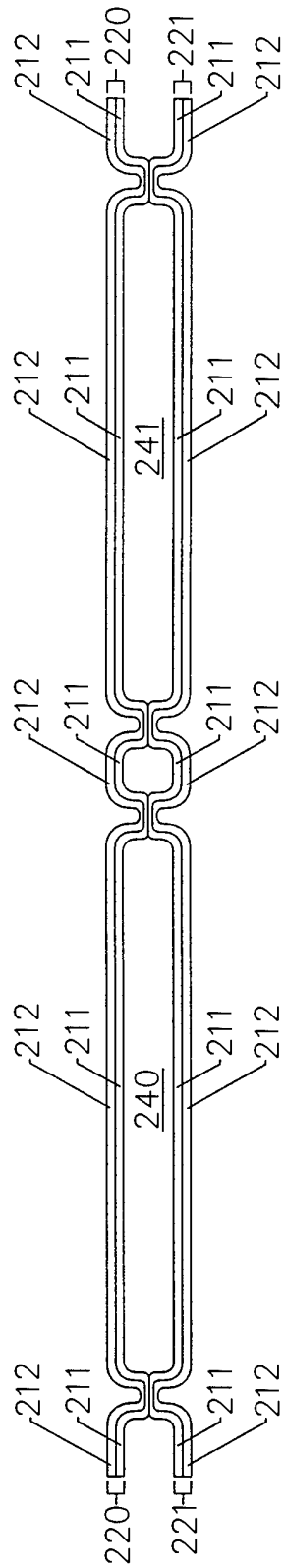


FIG. 6.

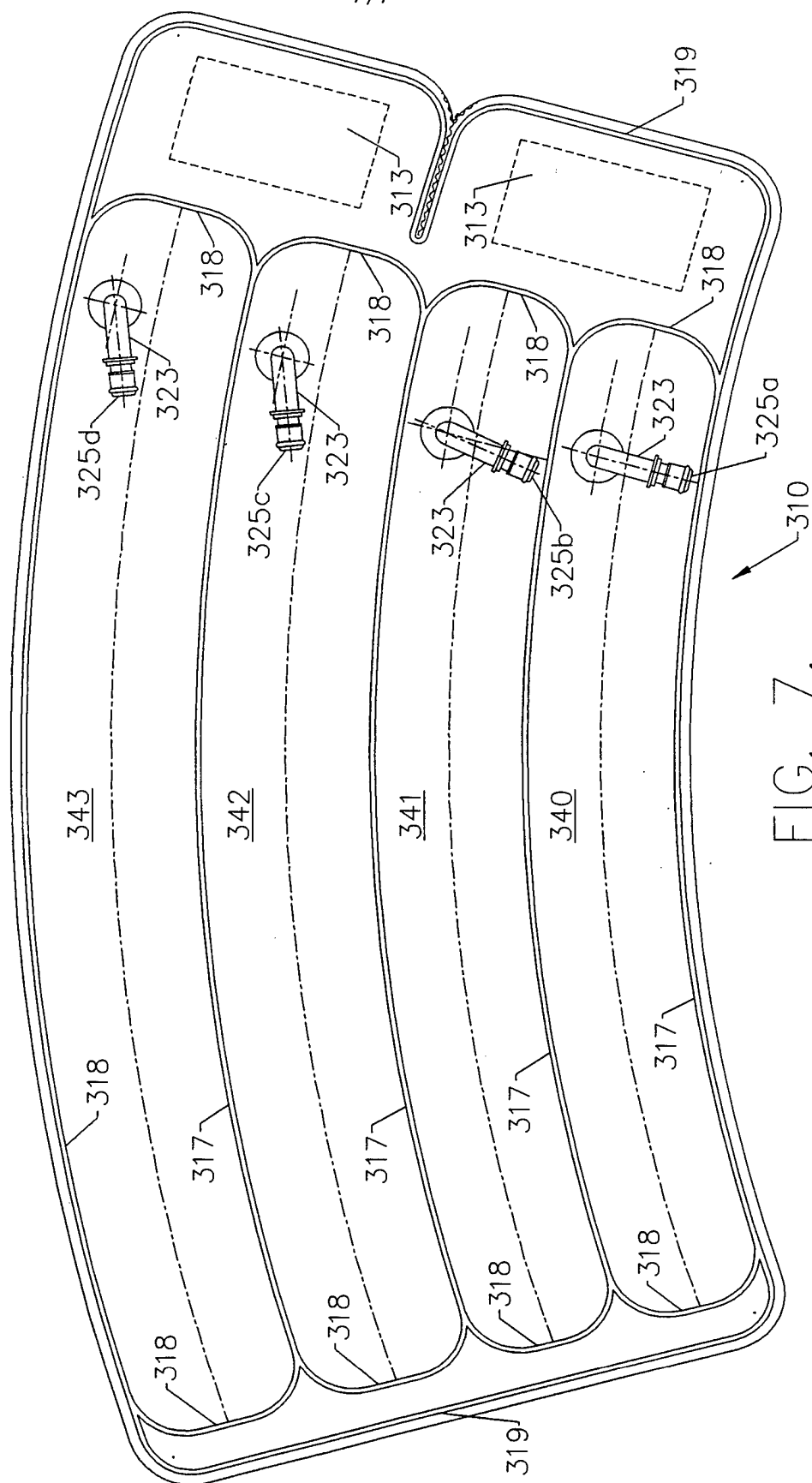


FIG. 7.

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 95/03646

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61H9/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,4 280 485 (ARKANS EDWARD J) 28 July 1981	1-3,5-8, 10,11, 13,17, 20,22, 23,25, 27-29
Y	see column 3, line 6 - line 52; figures 1-9	4,9,12, 16,18, 19,21, 24,26
Y	--- US,A,4 597 384 (WHITNEY JOHN K) 1 July 1986 see column 3, line 13 - line 18; figures 1,2 --- -/--	4,12,16, 26

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

19 July 1995

Date of mailing of the international search report

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# INTERNATIONAL SEARCH REPORT

International Application No  
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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP,A,0 388 200 (KENDALL & CO) 19 September 1990 see column 12, line 13 - column 13, line 48; figures 1-5 ---	9,18,19, 21
Y	US,A,4 773 397 (WRIGHT EDWARD S ET AL) 27 September 1988 see column 4, line 31 - line 34; figure 1 ---	24
A	US,A,4 402 312 (VILLARI FRANK K ET AL) 6 September 1983 see column 3, line 28 - line 43; figure 2 -----	14,15

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Interr. al Application No

PCT/US 95/03646

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-4280485	28-07-81	CA-A- 1155019	11-10-83
US-A-4597384	01-07-86	NONE	
EP-A-0388200	19-09-90	US-A- 4938208	03-07-90
		US-A- 5031604	16-07-91
		US-A- 5007411	16-04-91
		US-A- 4966396	30-10-90
		AT-T- 111337	15-09-94
		AU-B- 628917	24-09-92
		AU-A- 4913190	20-09-90
		CA-A- 2009840	16-09-90
		DE-D- 69012381	20-10-94
		DE-T- 69012381	11-05-95
		ES-T- 2060024	16-11-94
		JP-A- 3047258	28-02-91
		AT-T- 105706	15-06-94
		AU-B- 624898	25-06-92
		AU-A- 4913090	18-10-90
		CA-A- 2009834	12-10-90
		DE-D- 69008919	23-06-94
		DE-T- 69008919	15-12-94
		EP-A- 0392670	17-10-90
		ES-T- 2053102	16-07-94
		JP-A- 3149047	25-06-91
		AU-B- 629293	01-10-92
		AU-A- 4913290	18-10-90
		CA-A- 2009832	12-10-90
		EP-A- 0392669	17-10-90
		JP-A- 3029656	07-02-91
		AT-T- 109344	15-08-94
		AU-B- 623497	14-05-92
		AU-A- 5005590	18-10-90
		CA-A- 2009833	13-10-90
		DE-D- 69011175	08-09-94
		DE-T- 69011175	16-03-95
		EP-A- 0393833	24-10-90
		ES-T- 2057375	16-10-94
		JP-A- 3014994	23-01-91

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Interr. Application No

PCT/US 95/03646

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-4773397	27-09-88	US-A- 4922893	08-05-90
US-A-4402312	06-09-83	NONE	